

Department of Defense DIRECTIVE

NUMBER 6485.1 March 19, 1991

Incorporating Change 1, August 10, 1992

ASD(HA)

SUBJECT: Human Immunodeficiency Virus-1 (HIV-1)

References: (a) Deputy Secretary of Defense Memorandum, "Policy on Identification, Surveillance, and Administration of Personnel Infected with Human Immunodeficiency Virus (HIV)," August 4, 1988 (hereby canceled)

- (b) Deputy Secretary of Defense Memorandum "Recommendations for Revision of DoD Human Immunodeficiency Virus (HIV) Policies," March 8, 1988 (hereby canceled)
- (c) Assistant Secretary of Defense (Health Affairs) Memorandum, "Policy on Clinical Evaluation, Staging and Disease Coding of Military Personnel Infected with Human Immunodeficiency Virus (HIV)," September 11, 1987 (hereby canceled)
- (d) Assistant Secretary of Defense (Health Affairs) Memorandum, "The DoD HTLV-III Testing Program," December 5, 1985 (hereby canceled)
- (e) through (p), see enclosure 1

1. PURPOSE

This Directive supersedes references (a) through (f) to update policy, responsibilities, and procedures on identification, surveillance, and administration of civilian and military personnel infected with HIV-1.

2. APPLICABILITY

This Directive applies to the Office of the Secretary of Defense, the Military Departments (including their Reserve components), the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Unified and Specified Commands, and the Defense Agencies (hereafter referred to collectively as "the DoD Components"). The term "Military Services," as used herein, refers to the Army, the Navy, the Air Force, and the Marine Corps.

3. DEFINITIONS

- 3.1. <u>Human Immunodeficiency Virus-1 (HIV-1)</u>. The virus most commonly associated with the Acquired Immune Deficiency Syndrome (AIDS) in the United States.
- 3.2. <u>HIV-1 and/or AIDS Education Program</u>. Any combination of information, education, and behavior-change strategies designed to facilitate behavioral alteration that will improve or protect health. Included are those activities intended to support or influence individuals in managing their own health through lifestyle decisions and self-care. Operationally, such programs include community, worksite, and clinical aspects using appropriate public health education methodologies.
- 3.3. <u>Serologic Evidence of HIV-1 Infection</u>. A reactive result given by a Food and Drug Administration (FDA)-approved enzyme-linked immunosorbent assay (ELISA) serologic test that is confirmed by a reactive and diagnostic immunoelectrophoresis test (Western blot (WB)) test on two separate samples.
- 3.4. <u>Host Nation</u>. A foreign nation to which DoD U.S. civilian employees are assigned to perform their official duties.
- 3.5. <u>DoD Civilian Employees</u>. Current and prospective DoD U.S. civilian employees, including appropriated and nonappropriated fund personnel. This does not include members of the family of DoD civilian employees, employees of, or applicants for, positions with contractors performing work for the Department of Defense, or their families.
- 3.6. <u>Epidemiological Assessment</u>. The process by which personal and confidential information on the possible modes of transmission of HIV-1 are obtained from an HIV-1 infected person. This information is used to determine if previous, present, or future contacts of the infected individual are at risk for infection with HIV-1 and to prevent further transmission of HIV-1.

4. POLICY

It is DoD policy to:

- 4.1. Deny eligibility for appointment or enlistment for Military Service to individuals with serologic evidence of HIV-1 infection.
- 4.2. Screen active duty (AD) and Reserve component military personnel periodically for serologic evidence of HIV-1 infection.
- 4.3. Refer AD personnel with serologic evidence of HIV-1 infection for a medical evaluation of fitness for continued service in the same manner as personnel with other progressive illnesses, as specified in DoD Directive 1332.18 (reference (g)). Medical evaluation shall be conducted in accordance with the standard clinical protocol, as described in enclosure 2. Individuals with serologic evidence of HIV-1 infection who are fit for duty shall not be retired or separated solely on the basis of serologic evidence of HIV-1 infection. AD personnel with serological evidence of HIV-1 infection or who are ELISA repeatedly reactive, but WB negative or indeterminate, shall be advised to refrain from donating blood.
- 4.4. Deny eligibility for extended AD (duty for a period of more than 30 days) to those Reserve component members with serologic evidence of HIV-1 infection (except under conditions of mobilization and on the decision of the Secretary of the Military Department concerned). Reserve component members who are not on extended AD or who are not on extended full-time National Guard duty, and who show serologic evidence of HIV-1 infection, shall be transferred involuntarily to the Standby Reserve only if they cannot be utilized in the Selected Reserve.
- 4.5. Retire or separate AD or Reserve Service members infected with HIV-1 who are determined to be unfit for further duty, as implemented in reference (g).
- 4.6. Ensure the safety of the blood supply through policies of the Armed Services Blood Program Office, the FDA guidelines, and the accreditation requirements of the American Association of Blood Banks.
- 4.7. Comply with applicable statutory limitations on the use of the information obtained from a Service member during, or as a result of, an epidemiological assessment interview and the results obtained from laboratory tests for HIV-1, as provided in this Directive. (See enclosure 3.)

- 4.8. Control transmission of HIV-1 through an aggressive disease surveillance and health education program.
- 4.9. Provide education and voluntary HIV-1 serologic screening for DoD healthcare beneficiaries (other than Service members).
- 4.10. Comply with host-nation requirements for HIV-1 screening of DoD civilian employees, as described in enclosure 8.

5. RESPONSIBILITIES

- 5.1. The <u>Assistant Secretary of Defense (Health Affairs)</u>, in coordination with the Assistant Secretary of Defense (Force Management and Personnel) (ASD(FM&P)), the General Counsel of the Department of Defense (GC, DoD), and the Assistant Secretary of Defense (Reserve Affairs), is responsible for establishing policies, procedures, and standards for the identification, surveillance, and administration of personnel infected with HIV-1. The Assistant Secretary of Defense (Health Affairs) (ASD(HA)) shall provide overall policy guidance and approval for the HIV-1 and/or AIDS education and information efforts and shall establish the HIV-1 and/or AIDS Information and Education Coordinating Committee.
- 5.2. The <u>Secretaries of the Military Departments</u> shall establish Service policies, procedures, and standards for the identification, surveillance, education, and administration of personnel infected with HIV-1, based on and consistent with all sections of this Directive.
- 5.3. The <u>Assistant Secretary of Defense (Force Management and Personnel)</u> shall establish and revise policies governing HIV-1 screening of DoD civilian employees assigned to, performing official travel in, or deployed on ships with ports of call at host nations, in coordination with the ASD(HA), the Assistant Secretary of Defense (International Security Affairs), and the GC, DoD.
- 5.4. The <u>Assistant Secretary of Defense (International Security Affairs)</u> shall identify or confirm host-nation HIV-1 screening requirements for DoD civilians, transmit this information to the ASD(FM&P), and coordinate requests for screening with the Department of State.
- 5.5. The <u>Heads of the DoD Components</u> shall implement HIV-1 screening policies and procedures for DoD civilian employees identified in paragraph 5.3., above, and shall take the following actions:

- 5.5.1. Report newly established host-nation HIV-1 screening requirements to the ASD(FM&P) and provide sufficient background information to support a decision. This reporting requirement is exempt from licensing, in accordance with DoD 7750.5-M, subparagraph 5.4.2. (reference (h)).
 - 5.5.2. Develop and distribute policy implementing instructions.
- 5.5.3. Establish procedures to notify individuals who are evaluated as HIV-1 seropositive and provide initial counseling to them.

6. PROCEDURES

- 6.1. Applicants for Military Service and, periodically, AD and Reserve component military personnel shall be screened for serologic evidence of HIV-1 infection. Testing and interpretation of results shall be in accordance with the procedures in enclosure 4. Test results shall be reported to the Reportable Disease Database, as described in the ASD(HA) Memorandum (reference (i)).
- 6.2. Applicants for enlisted service shall be screened at the Military Entrance Processing Stations or the initial point of entry to Military Service. Applicants who enlist under a delayed enlistment program, but before entry on AD and who exhibit serologic evidence of HIV-1 infection, may be discharged due to erroneous enlistment.
- 6.3. Officer candidates shall be screened during their preappointment and/or pre-contracting physical examination. The disposition of officer applicants who are ineligible for appointment due to serologic evidence of HIV-1 infection shall be in accordance with the procedures in enclosure 5.
- 6.4. Applicants for Reserve components shall be screened during the normal entry physical examinations or in the pre-appointment programs established for officers. Those individuals with serologic evidence of HIV-1 infection who are required to meet accession medical fitness standards to enlist, or be appointed, are not eligible for Military Service with the Reserve components.
- 6.5. Initial testing and periodic retesting of AD and Reserve component personnel shall be accomplished in the priority listed in enclosure 6.

- 6.6. AD personnel (including Active Guard and/or Reserve) who exhibit serologic evidence of HIV-1 infection shall receive a medical evaluation in accordance with the procedures in enclosures 2, 6, and 7. Guard and Reserve personnel, not on extended AD, must obtain a medical evaluation from a civilian physician.
- 6.7. The Head of each Military Service shall appoint an HIV-1 and/or AIDS education program coordinator to serve as the focal point for all HIV-1 and/or AIDS education program issues and to integrate the educational activities of the medical and personnel departments.
- 6.8. An HIV-1 and/or AIDS Information and Education Coordinating Committee shall be established to enhance communication among the Military Services, recommend joint education policy and program actions, review education program implementation, and recommend methodologies and procedures for program evaluation. That committee shall be chaired by a representative of the ASD(HA). Members shall include two representatives from the Office of the ASD(FM&P) and the HIV-1 and/or AIDS education program coordinator from each Military Service. Additional members shall represent the Armed Services Blood Program Office and, on an ad hoc basis, the OASD(HA). Policy and program proposals shall be coordinated with the Secretaries of the Military Departments.
- 6.9. The Head of each Military Service shall prepare a plan for the implementation of a comprehensive HIV-1 and/or AIDS education program that includes specific objectives with measurable action steps. The plan shall address information, education, and behavior-change strategies, as described in enclosure 6.
- 6.10. Civilians may not be mandatorily tested for serologic evidence of HIV-1 infection except as necessary to comply with valid host-nation requirements for screening of DoD employees. Procedures for mandatory screening of DoD civilians shall be in accordance with enclosure 8.
- 6.11. The medical assessment of each exposure to, and/or case of, HIV-1 infection seen at a military medical treatment facility (MTF) shall include an epidemiological assessment of the potential transmission of HIV-1 to other persons at risk of infection, including sexual and other intimate contacts and family of the patient, and transfusion history. The occurrence of HIV-1 infection or serologic evidence of HIV-1 infection may not be used as a basis for any disciplinary action against an individual, except as described in enclosure 3.

- 6.12. Each military medical service shall conduct an ongoing clinical evaluation of each AD Service member with serologic evidence of HIV-1 infection at least annually. CD4 lymphocyte percentages or counts shall be monitored at least every 6 months. Appropriate preventive medicine counseling shall also be provided to all individual patients and public health education materials shall be made available to that medical services' beneficiary population. Each military medical service shall conduct longitudinal clinical evaluations of AD Service members with serologic evidence of HIV-1 infection and shall prepare internal reports to facilitate timely review and reassessment of current policy guidelines.
- 6.13. All military MTFs shall notify promptly the cognizant military health authority, when there is clinical or laboratory evidence indicative of infection with HIV-1 in accordance with enclosure 9.
- 6.14. The Secretary of each Military Department shall ensure that a mechanism is established to gather data on the epidemiology of HIV-1 infection of its members. Such epidemiological research shall be accomplished to ensure appropriate protection of information given by the Service member on the means of transmission.
- 6.15. The Department of the Army, as the Lead Agency for infectious disease research within the Department of Defense, shall budget for and fund tri-Military Department DoD HIV-1 research efforts, in accordance with guidance provided by the ASD(HA). The research program shall focus on the epidemiology and natural history of HIV-1 infections in military and military associated populations; on improving the methods for rapid diagnosis and patient evaluation; and on studies of the immune response to HIV-1 infection, including the potential for increased risk in the military operational environment.
- 6.16. Service members with serologic evidence of HIV-1 infection shall be assigned within the United States, including Alaska, Hawaii, and Puerto Rico, due to the high priority assigned to the continued medical evaluation of military personnel. The Secretaries of the Military Departments may restrict such individuals to non-deployable units or positions for purposes of force readiness. To protect the health and safety of Service members with serologic evidence of HIV-1 infection and of other Service members (and for no other reason), the Secretaries of the Military Departments may, on the basis of an evaluation consistent with established Service procedures for other medical conditions, limit assignment of HIV-1-infected individuals on the nature and location of the duties performed in accordance with operational requirements.

- 6.17. AD and Reserve component personnel with serologic evidence of HIV-1 infection shall be retained or separated in accordance with enclosure 10.
- 6.18. The ASD(HA), in coordination with the Heads of the Military Services, shall revise enclosures 2, 4, 6, and 7, as appropriate. The ASD(FM&P) shall revise enclosure 8, as appropriate. Revisions under this paragraph shall be coordinated with GC, DoD. The ASD(HA) shall issue policy guidance on the prevention of HIV-1 transmission to patients during exposure-prone invasive procedures.

7. <u>EFFECTIVE DATE AND IMPLEMENTATION</u>

This Directive is effective immediately. Forward two copies of implementing documents to the Assistant Secretary of Defense (Health Affairs) within 90 days.

Donald J. Atwood

Deputy Secretary of Defense

Tomald fatures

Enclosures - 10

- E1. References, continued
- E2. Standard Clinical Protocol
- E3. Limitations on the Use of Information
- E4. HIV-1 Testing and Interpretation of Results
- E5. Administration of Officer Applicants
- E6. Disease Surveillance and Health Education
- E7. Procedure for Evaluating T-Helper Cell Count
- E8. HIV-1 Testing of DoD Civilian Employees
- E9. Personnel Notification and Epidemiological Investigation
- E10. Retention and Separation

E1. ENCLOSURE 1

<u>REFERENCES</u>, continued

- (e) Assistant Secretary of Defense (Health Affairs) Memorandum, "Military Implementation of Public Health Service Provisional Recommendations Concerning Testing Blood and Plasma for Antibodies to HTLV-III," July 17, 1985 (hereby canceled)
- (f) DoD Instruction 1438.4, "Compliance with Host Nation Human Immunodeficiency Virus (HIV) Screening Requirements for DoD Civilian Employees," December 5, 1988 (hereby canceled)
- (g) <u>DoD Directive 1332.18</u>, "Separation from the Military Service by Reason of Physical Disability," February 25, 1986
- (h) DoD 7750.5-M, "DoD Procedures for Management of Information Requirements," November 1986
- (i) Assistant Secretary of Defense (Health Affairs) Memorandum, "DoD Reportable Disease Database," December 30, 1985
- (j) Chapter 47 of title 10, United States Code, "Uniform Code of Military Justice (UCMJ)"
- (k) Assistant Secretary of Defense (Force Management and Personnel) Memorandum, "Information and Guidance on Human Immunodeficiency Virus (HIV)," January 22, 1988
- (1) Federal Personnel Manual Bulletin 792-42, "AIDS in the Workplace, March 24, 1988
- (m) Section 794 of title 29, United States Code, "Section 504 of the Rehabilitation Act of 1973," as amended
- (n) <u>DoD Directive 5400.11</u>, "Department of Defense Privacy Program," June 9, 1982
- (o) Assistant Secretary of Defense (Health Affairs) Memorandum, "HIV Testing and Look Back Guidelines for Homologous Blood Donations," January 11, 1989
- (p) Public Law 93-579, "Privacy Act of 1974," December 31, 1974 (5 U.S.C. 552a)

E2. ENCLOSURE 2

STANDARD CLINICAL PROTOCOL

E2.1. MEDICAL EVALUATION

- E2.1.1. A complete medical evaluation shall be accomplished, at least annually, and T-cell subset evaluation at least every 6 months, on military personnel with serologic evidence of HIV-1 infection. This medical evaluation shall be documented in a manner consistent with the Head of the Medical Evaluation Board requirements of each Service.
 - E2.1.2. Minimally, the medical workup shall include the following:
 - E2.1.2.1. An epidemiological assessment.
- E2.1.2.2. History and physical examination, to include a neurological and neuropsychiatric evaluation.
- E2.1.2.3. Complete blood count with differential, platelet count, red blood cell indices, and erythrocyte sedimentation rate.
- E2.1.2.4. Total lymphocyte count, total T-lymphocyte cell count, and absolute CD4 and CD8 levels.
- E2.1.2.5. Intradermal skin tests (intermediate purified protein derivative standard tuberculin units, mumps 40 colony forming units (CFU) per milliliter (ml), trichophyton 1:30, candida 1:10, and tetanus 1:10).
 - E2.1.2.6. HIV-1 ELISA and confirmation test.
- E2.1.2.7. Chest x-ray (posterior-anterior and lateral) on the initial evaluation. Subsequent chest x-rays shall be ordered when clinically indicated.
- E2.1.3. Because of the strong association of HIV-1 infection with other sexually transmitted diseases, the workup minimally shall include evaluative tests for syphilis, hepatitis, urethritis, cervicitis, or proctitis.
- E2.1.4. The Surgeon General of each Military Department shall designate DoD Component military MTFs, which are to be used to evaluate and treat individuals with serologic evidence of HIV-1 infection. The initial evaluation and annual reevaluation of Service members with serologic evidence of HIV-1 infection shall ordinarily be

accomplished within the individual's respective Military Department. In the case of symptomatic individuals, subsequent hospitalizations or continuation of care following the initial evaluation may be at any designated MTF within the Department of Defense.

- E2.1.5. A frozen blood specimen on all HIV-1-positive individuals shall be maintained for at least 3 years at -70 Celsius. The Military Departments shall maintain central serum banks.
- E2.1.6. A mental health assessment and social history shall be elicited that includes current emotional and social support, depression, interpersonal relationships, and work adjustment. Sociodemographic and psychosocial risk factors relating to suicide, drug and alcohol abuse, and major mental illness shall be emphasized. Subtle signs of dementia shall also be sought.
- E2.1.6.1. The mental health evaluation may be performed by a psychiatric nurse, psychiatric social worker, psychologist, trained nonpsychiatric physician, or psychiatrist, depending on local MTF resources.
- E2.1.6.2. Specific diagnostic and treatment modalities shall depend on clinical and research resources at each site, but may include psychiatric rating scales and behavioral intervention strategies. Examples of testing methods that shall be employed include the following: Beck Depression Index, Michigan Alcohol Screening Test, Perceived Social Support Questionnaire, Symptom Check List 90-Revised, Wechsler Memory Scale-Revised, Halstead-Reitan, and Trailmaking B.
- E2.1.6.3. Psychiatric consultation shall be sought for further evaluation, if concerns exist for fitness for duty, or if this screening evaluation suggests that more detailed psychiatric evaluation is needed. If the patient has persistent evidence of diminished intellectual skills, personality changes, and motor impairment, the patient shall require specialized studies (neurologic studies, computed tomography or magnet resonance imaging, lumbar puncture, psychiatric examination, and neuropsychologic testing) to evaluate the possible presence of a HIV-1-related mental or neurological syndrome.

E2.2. ARMED FORCES HIV-1 DISEASE CLASSIFICATION

E2.2.1. All patients with either serologic evidence of HIV-1 infection or a positive virus isolation shall be staged according to the following scheme:

_	HIV-1 Antibody	_	T-Helper Cells per	<u>Delayed</u>	_	_
_	and/or Virus	Chronic Lymph-	Cubic Millimeter	Hyper-	_	Opportunistic
<u>Stage</u>	<u>Isolation</u>	<u>adenopathy</u>	(mm ³)	<u>sensitivity</u>	<u>Thrush</u>	<u>Infection</u>
1	+	-	GT400	WNL		
2	+	+	GT400	WNL		
3	+	+/-	LT400	WNL		
4	+	+/-	LT400	Р		
5	+	+/-	LT400	P/C	+	
6	+	+/-	LT400	P/C	+/-	+
(GT = greater than I T = less than)						

(GT = greater than, LT = less than)

- E2.2.2. Because of the natural variability of the number of T-helper cells, classification of HIV-1 infections shall not be based on a single T-helper cell determination. A second count at an interval of at least 1 month is required if the initial CD4 absolute number is less than 400 cells per mm³. The higher of the two counts shall be used for staging. All HIV-1-infected personnel shall have CD4 lymphocyte percentages or counts monitored at least every 6 months.
- E2.2.3. There are a small number of patients who cannot be readily staged using the scheme in section E2.2. of this enclosure, above. When a patient falls between two stages the lower stage shall be selected; e.g., select stage 4, if patient falls between stages 4 and 5.
- E2.2.4. Stages 1 through 6 require demonstration of the presence of HIV-1antibody to structural proteins and/or HIV-1 virus isolation.
- E2.2.5. An individual will occasionally be found with at least 400 T-helper cells per mm³ who demonstrates partial or complete cutaneous anergy. In staging, if the CD4 number is 400 cells per mm³, or greater, the individual shall be placed in stage 1 or 2.
- E2.2.6. Stage 5 is defined by the occurrence of either complete anergy, or thrush, microscopically confirmed in a patient with less than 400 CD4 cells per mm³.
- E2.2.7. The presence of symptoms is denoted by the addition of the letter B after the stage; e.g., stage 5B. Symptoms are defined as fever greater than 100.5 Fahrenheit

- for 3 weeks, unexplained weight loss of greater than 10 percent of body weight over 3 months, night sweats for at least 3 weeks, or chronic diarrhea for at least 1 month. Many of these patients can be documented to have an occult opportunistic infection (OI) by a careful and complete reevaluation.
- E2.2.8. Kaposi's sarcoma is designated by adding the letter K after the appropriate class; e.g., stage 4K. Current evidence suggests that this neoplastic process is not dependent on severe T-helper cell depletion.
- E2.2.9. The occurrence of other neoplasms is designated by adding the letter N after the appropriate class; e.g., stage 4N.
- E2.2.10. Central nervous system (CNS) HIV-1 is neurologic disease or secondary psychiatric disease (demyelinating disease, encephalopathy, and/or neuropathy) as a result of infection of the nervous system by HIV-1 and is designated by adding CNS after the appropriate stage; e.g., stage 4CNS. An abnormal cerebrospinal fluid (e.g., pleocytosis, increased cerebrospinal fluid protein, increased cerebrospinal fluid IgG, viral isolation, or oligoclonal bands) does not alone warrant this designation.
- E2.2.11. HIV-1 antibody is defined as the presence of antibody to the structural proteins of HIV-1, as determined by WB techniques or supplemental tests. (See enclosure 4, subparagraph E4.4.4.1.) HIV-1 virus isolation also fulfills criteria to document infection.
- E2.2.12. Chronic lymphadenopathy is defined as two or more extrainguinal sites with lymph nodes greater than, or equal to, 1 centimeter in diameter that persist for more than 3 months.
- E2.2.13. T-helper cells are expressed as cells per mm³. Quantitative depletion must be persistent for at least 1 month to be placed in stage 3 or a higher stage.
- E2.2.14. Delayed hypersensitivity is defined as within normal limits (WNL) when an intact cutaneous response (mean diameter of induration greater than, or equal to, 5 millimeters) to at least two of the following four intradermal test antigens is observed: tetanus 1:10, trichophyton 1:30, mumps 40 CFU per ml, and candida 1:10. A partial response is defined as an intact cutaneous response to only one of those four antigens. The letter "C"represents complete cutaneous anergy to all four test antigens.
- E2.2.15. Thrush is defined as clinical oral candidiasis including a positive potassium hydroxide (KOH) preparation or yeast seen on gram stain.

E2.2.16. OI is present when infections such as pneumocystis carinii pneumonia, CNS or disseminated toxoplasmosis, chronic cryptosporidiosis, candida esophagitis, disseminated histoplasmosis, CNS or disseminated cryptococcosis, disseminated atypical mycobacterial disease, extrapulmonary tuberculosis, disseminated nocardiosis, disseminated cytomegalovirus, or chronic mucocutaneous herpes simplex occur. Other disseminated or chronic nonself-limited infections with agents in which cellular immunity plays a pivotal role in host defense (i.e., viral, parasitic, fungal, mycobacterial, or certain other bacterial agents) should be anticipated to cause opportunistic disease in patients with stages 5 and 6. Kaposi's sarcoma solely does not fulfill staging criteria for stage 6.

E2.3. MEDICAL RECORD CODING OF HIV-1 INFECTIONS

The MTFs shall use both the 042-044 and 795.8 codes from the International Classification of Disease, 9th Revision, Clinical Modification (ICD-9-CM). The code extenders 795.8--1 to 795.8--9 were developed to support the DoD classification system to indicate staging. The appropriate 795.8 code shall be used when an individual is evaluated by a MTF. Per DoD disease and procedure classification ICD-9-CM coding guidelines, they can be used alone, following the initial screening process, or in conjunction with the 042-044 codes. The following 042-044 codes describe the site of infection and are compatible with civilian practice:

E2.3.1. These codes shall be used only on inpatient records:

<u>DESCRIPTION</u>
HIV-1 infection with specified infections
HIV-1 infection causing other specified infections
HIV-1 infection with specified malignant neoplasms
AIDS unspecified
HIV-1 infection causing lymphadenopathy
HIV-1 infection causing specified diseases of CNS
HIV-1 infection causing other disorders of immune mechanism
HIV-1 infection causing other specified conditions
AIDS-related complex with or without other conditions
HIV-1 infection causing specific acute infections
HIV-1 infection unspecified
HIV-1 (HIV-1 antibody positive stage 1 of infection)
As above, stage 2 of infection
As above, stage 3 of infection
As above, stage 4 of infection
As above, stage 5 of infection
As above, stage 6 of infection

E2.3.2. The following codes are no longer authorized for use, having been replaced by the 759.8 code with extenders, as in paragraph E2.3.1. of this enclosure, above. Records should be updated by replacing the following with the current approved code:

```
V73.71 HIV-1 antibody positive, stage 1 of infection
V73.72 As above, stage 2 of infection
V73.73 As above, stage 3 of infection
V73.74 As above, stage 4 of infection
V73.75 As above, stage 5 of infection
V73.76 As above, stage 6 of infection
V73.79 As above, stage of infection unspecified
```

E2.3.3. The following codes shall be used only on outpatient records:

- V72.60 Serologic test only HIV-1 antibody negative (ELISA or comparable screening test negative), a single positive ELISA that is negative and on repeat ELISA testing that is negative
- V72.61 Serologic test only HIV-1 antibody unconfirmed (repeatedly reactive ELISA with negative WB)
- V72.62 Serologic test only HIV-1 antibody positive (WB or comparable antibody assay positive)
- V72.69 Other laboratory examination

E2.4. DISPOSITION OF INDIVIDUALS INFECTED

- E2.4.1. Fitness for duty determinations shall be in accordance with DoD Directive 1332.18 (reference (g)). The fitness for duty determination shall not be based solely on the Armed Forces HIV-1 disease classification.
- E2.4.2. Service members infected with HIV-1 shall be referred to a Medical Evaluation Board, regardless of the clinical stage of the disease, if the Service member shows signs of immunological deficiency or a progressive illness. Signs of immunological deficiency include persistent reduction in the level of T-helper lymphocytes below 300 cells per mm³ for greater than 1 month without other demonstrable cause; reduced or absent delayed hyper-sensitivity, as measured by the standardized battery of skin tests (in association with other significant clinical findings); development of thrush; increased susceptibility to either common or uncommon infections; and more severe episodes of infection than usually seen with a given organism. Signs of a progressive clinical illness include development of neurological manifestations; Kaposi's sarcoma; other lymphoreticular malignancies; thrombocytopenia; diffuse, persistent lymphadenopathy; or unexplained weight loss, diarrhea, anorexia, fever, malaise, or fatigue. The Walter Reed staging system may not be the sole criterion for evaluations of fitness for duty in Medical Evaluation Board reports.

E3. ENCLOSURE 3

LIMITATIONS ON THE USE OF INFORMATION

E3.1. <u>LIMITATIONS OF RESULTS</u>

- E3.1.1. Results obtained from laboratory tests performed under this Directive may not be used as the sole basis for separation of a Service member. Those results may be used to support a separation based on physical disability or as specifically authorized by any section in this Directive. This paragraph shall not preclude use of such laboratory test results in any other manner consistent with law or regulation.
- E3.1.2. Laboratory test results confirming the serologic evidence of HIV-1 infection may not be used as an independent basis for any adverse administrative action or any disciplinary action, including punitive actions under the UCMJ (10 U.S.C. 47, reference (j)). However, such results may be used for other purposes including, but not limited to, the following:
 - E3.1.2.1. Separation under the accession testing program.
 - E3.1.2.2. Voluntary separation for the convenience of the Government.
 - E3.1.2.3. Other administrative separation action authorized by DoD policy.
- E3.1.2.4. In conducting authorized Armed Services Blood Program Look Back activities.
- E3.1.2.5. Other purposes (such as rebuttal or impeachment) consistent with law or regulation (e.g., the Federal or Military Rules of Evidence or the rules of evidence of a State), including to establish the HIV-1 seropositivity of a Service member when:
- E3.1.2.5.1. The Service member disregards the preventive medicine counseling or the preventive medicine order, or both, in an administrative or disciplinary action based on such disregard or disobedience.
- E3.1.2.5.2. HIV-1 infection is an element in any permissible administrative or disciplinary action, including any criminal prosecution (e.g., as an element of proof of an offense charged under the UCMJ (reference (j)), or under the code of a State or the United States).

E3.1.2.5.3. HIV-1 infection is a proper ancillary matter in an administrative or disciplinary action, including any criminal prosecution (e.g., as a matter in aggravation in a court-martial in which the HIV-1 positive Service member is convicted of an act of rape committed after being informed that he is HIV-1 positive).

E3.2. <u>LIMITATIONS ON THE USE OF INFORMATION OBTAINED IN THE</u> EPIDEMIOLOGICAL ASSESSMENT INTERVIEW

- E3.2.1. Information obtained from a Service member during, or as a result of, an epidemiological assessment interview may not be used against the Service member in the following:
 - E3.2.1.1. A court-martial.
 - E3.2.1.2. Line of duty determination.
 - E3.2.1.3. Nonjudicial punishment.
 - E3.2.1.4. Involuntary separation (other than for medical reasons).
 - E3.2.1.5. Administrative or punitive reduction-in-grade.
 - E3.2.1.6. Denial of promotion.
 - E3.2.1.7. An unfavorable entry in a personnel record.
 - E3.2.1.8. Abar to reenlistment.
- E3.2.1.9. Any other action considered by the Secretary of the Military Department concerned to be an adverse personnel action.
- E3.2.2. The limitations in paragraph E3.2.1. of this enclosure, above, do not apply to the introduction of evidence for appropriate impeachment or rebuttal purposes in any proceeding, such as one in which the evidence of drug abuse or relevant sexual activity (or lack, thereof) has been first introduced by the Service member or to disciplinary or other action based on independently derived evidence.
- E3.2.3. The limitations in paragraph E3.2.1. of this enclosure, above, do not apply to, the basis of an evaluation consistent with established Service procedures for other medical conditions, non-adverse personnel actions, such as:

- E3.2.3.1. Reassignment.
- E3.2.3.2. Disqualification (temporary or permanent) from a personnel reliability program.
 - E3.2.3.3. Denial, suspension, or revocation of a security clearance.
 - E3.2.3.4. Suspension or termination of access to classified information.
- E3.2.3.5. Removal (temporary or permanent) from flight status or other duties requiring a high degree of stability or alertness, including explosive ordnance disposal or deep-sea diving.

E3.3. GENERAL

Except as authorized by this Directive, if any such personnel actions are taken because of, or are supported by, serologic evidence of HIV-1 infection or information described in section E3.1. of this enclosure, above, no unfavorable entry may be placed in a personnel record for such actions. Recording a personnel action is not an unfavorable entry in a personnel record. Additionally, information reflecting that an individual has serologic or other evidence of infection with HIV-1 is not an unfavorable entry in a personnel record.

E4. ENCLOSURE 4

HIV-1 TESTING AND INTERPERTATION OF RESULTS

E4.1. <u>LABORATORIES</u>

- E4.1.1. Either in-house or contract laboratories shall be used to perform the initial screening test on specimens collected from Service members.
- E4.1.2. Confirmatory testing shall be limited to as few laboratories per Service as possible, since the confirmatory test is subjective and tight controls must be maintained on both the procedure and interpretation of results.
- E4.1.3. After awarding a contract, final approval of the laboratory shall be contingent on an inspection by the appropriate Military Service. The laboratory must correctly identify 95 percent of the samples in an open panel (20 specimens) provided by a DoD reference laboratory. The inspection shall focus on the laboratory facilities, standard operation procedure manuals, training of technicians, specimen handling procedures, reporting capabilities, and internal quality control procedures.
- E4.1.4. The Heads of the Military Services shall ensure the conduct of a semiannual quality assurance inspection of each contract laboratory.
- E4.1.5. All specimens positive on the confirmatory test shall be stored frozen in the Services' central serum bank.

E4.2. SPECIMEN COLLECTION AND HANDLING

- E4.2.1. Blood samples shall be collected using appropriate vacutainer tubes.
- E4.2.2. Minimally, each sample shall have a label containing the individual's social security number, the date and time of collection, and a laboratory assigned number.
- E4.2.3. Samples shall be centrifuged and serum separated within 6 hours of collection.

- E4.2.4. Specimens shall be refrigerated before the initial test. If the initial test is not conducted within 7 days, or the date at which the sample was collected is unknown, the specimen shall be frozen.
- E4.2.5. Cold packs shall be used to maintain specimens at refrigerated temperatures during transit between laboratories.

E4.3. <u>INITIAL TEST</u>

- E4.3.1. The initial test shall be conducted using an FDA-approved ELISA test kit and results interpreted according to the manufacturer's package insert.
- E4.3.2. The laboratory shall establish an internal quality control program that includes a minimum total of 10 percent quality control samples per batch (e.g., standards, negatives, positive controls, and blind samples).
- E4.3.3. All controls and blinds shall be 100-percent correct before the entire batch results are considered acceptable.

E4.4. CONFIRMATORY TEST

- E4.4.1. Each laboratory performing the WB test shall conduct the test using a FDA-approved procedure.
- E4.4.2. Minimally, the laboratory shall validate its procedure using a protocol that establishes the accuracy, precision, and reproducibility of the method.
- E4.4.3. The internal quality control program shall include a minimum total of 20-percent quality control samples (e.g., standards, negatives, positive controls, or blind samples).
 - E4.4.4. WB test results shall be interpreted, as follows:
- E4.4.4.1. Positive, when it exhibits at least two of three bands at p24, gp41, and gp120 and/or 160.
 - E4.4.4.2. Negative, when it exhibits no bands.

E4.4.4.3. An indeterminate shall be resolved using nondiagnostic tests of a different technology. The following scheme shall be used to report results when supplemental testing is conducted to resolve nondiagnostic WB results:

<u>Lab Test</u>				<u>Re</u>	<u>sult</u>		
First ELISA	-	+	+	+	+	+	+
Second and/or third ELISA		-	+	+	+	+	+
WB			-	+	+/-	+/-	+/-
Supplemental					-	+	+/-
Laboratory Report	-	-	-	+	-	+	-
+ = positive = negative +/- = nondiagnostic							

E4.5. REFERENCE LABORATORY AND EXTERNAL PROFICIENCY TESTING

- E4.5.1. The Secretaries of the Military Departments shall establish a reference laboratory to provide panels of specimens to its blood banks conducting ELISA testing, to its contract laboratories conducting WB testing, and to the reference laboratories of the other Services.
- E4.5.2. The open panels shall consist of 20 specimens containing approximately 50-percent negatives and 50-percent positives.
- E4.5.3. The panels shall be provided at least quarterly. Each laboratory shall report correctly 95 percent of the samples.
- E4.5.4. The Secretaries of the Military Departments shall retain the responsibility to interpret all confirmatory results on specimens analyzed by contract laboratories.
- E4.5.5. The specific requirements, determined by each Military Department, for the external proficiency testing program (number of blind and open samples, frequency criteria for acceptable performance, etc.) shall depend on the workload of each laboratory doing confirmatory testing.

E5. ENCLOSURE 5

ADMINISTRATION OF OFFICER APPLICANTS

Administration of officer applicants who are ineligible for appointment, due to serologic evidence of HIV-1 infection, shall be in accordance with the following provisions:

- E5.1.1. Enlisted members who are candidates for appointment through Officer Candidate School (OCS) or Officer Training School (OTS) programs shall be disenrolled immediately from the program. If OCS and/or OTS is the individual's initial entry training, the individual shall be discharged. If the sole basis for discharge is serologic evidence of HIV-1 infection, an honorable or entry-level discharge, as appropriate, shall be issued. A candidate who has completed initial entry training during the current period of service before entry into candidate status shall be administered in accordance with Service regulations for enlisted personnel.
- E5.1.2. Individuals in pre-appointment programs, such as Reserve Officer Training Corps (ROTC) and Health Professions Scholarship Program participants, shall be disenrolled from the program. However, the Head of the Military Service concerned, or the designated representative, may delay disenrollment to the end of the academic term (i.e., semester, quarter, or similar period) in which serologic evidence of HIV-1 infection is confirmed. Disenrolled participants shall be permitted to retain any financial support through the end of the academic term in which the disenrollment is effected. Financial assistance received in these programs is not subject to recoupment, if the sole basis for disenrollment is serologic evidence of HIV-1 infection.
- E5.1.3. Service academy cadets, midshipmen, and personnel attending the Uniformed Services University of the Health Sciences (USUHS) shall be separated from the respective Service academy or USUHS and discharged. The Head of the Military Service concerned, or the designated representative, may delay separation to the end of the current academic year. A cadet or midshipman granted such a delay in the final academic year, who is otherwise qualified, may be graduated without commission and, thereafter, discharged. If the sole basis for discharge is serologic evidence of HIV-1 infection, an honorable discharge shall be issued.
- E5.1.4. Commissioned officers in DoD-sponsored professional education programs leading to appointment in a professional military specialty (including, but not limited to, medical, dental, chaplain, and legal and/or judge advocate) shall be disenrolled from the program at the end of the academic term in which serologic

evidence of HIV-1 infection is confirmed. Disenrolled officers shall be administered in accordance with Service regulations. Except as specifically prohibited by statute, any additional Service obligation incurred by participation in such programs shall be waived, and financial assistance received in these programs shall not be subject to recoupment. Periods spent by such officers in these programs shall be applied fully toward satisfaction of any preexisting Service obligation.

E5.1.5. All personnel disenrolled from officer programs who are to be separated shall be given appropriate counseling, to include preventive medicine counseling and advice to seek treatment from a civilian physician.

E6. ENCLOSURE 6

DISEASE SURVEILLANCE AND HEALTH EDUCATION

E6.1. GENERAL

Prevention of harm to personnel with serologic evidence of HIV-1 infection and control of transmission of HIV-1, a communicable disease, are dependent on an aggressive disease surveillance and health education program. Those persons whose behaviors put them and others at high risk of infection, followed by those who are infected, shall receive the highest priority for information, education, and behavior change programs.

E6.2. <u>DISEASE SURVEILLANCE</u>

- E6.2.1. Periodic retesting of military personnel shall be accomplished in the following priority order:
- E6.2.1.1. Military personnel serving in, or subject to deployment on short notice to, areas of the world with a high risk of endemic disease or with minimal existing medical capability.
- E6.2.1.2. Military personnel serving in, or pending assignment to, all other overseas permanent duty stations.
 - E6.2.1.3. Military personnel serving in units subject to deployment overseas.
- E6.2.1.4. Other military personnel or units deemed appropriate by the respective Military Department, such as medical personnel involved in the care of HIV-1 infected patients, patients being treated for sexually transmitted diseases or presenting at sexually transmitted disease clinics, patients being treated for alcohol and drug abuse or admitted to alcohol and drug rehabilitation units, and patients at prenatal clinics.
- E6.2.1.5. All remaining military personnel in conjunction with routinely scheduled periodic physical examinations.

- E6.2.2. AD personnel (to include Active Guard and/or Reserve and/or Selected Reserve) with serologic evidence of HIV-1 infection shall receive a medical evaluation to determine the status of their potential infection and the potential adverse consequences to the individual of serving in a particular geographic region. The standard clinical protocol in enclosure 2 shall be used to ensure consistent evaluation and classification of patients at all military MTFs. Documentation of the medical evaluation shall be equivalent to the medical board component of the Physical Evaluation Board process.
- E6.2.3. Reserve component members not on extended AD are ineligible for medical evaluation (beyond initial testing and counseling) in military MTFs. Therefore, those Reserve component individuals shall be counseled on the significance of a positive HIV-1 antibody test and referred to their private physicians for medical care and counseling.
- E6.2.4. The surveillance of military personnel for HIV-1 infection is being accomplished for force readiness reasons. It is also essential that all reasonable efforts be made to afford protection and education to our other healthcare beneficiaries on effective means to contain this disease.
- E6.2.5. For medical and public health purposes, an appropriate and vigorous HIV-1 and/or AIDS education program and voluntary HIV-1 serologic screening program shall be offered to all beneficiaries of the military healthcare system, in accordance with published recommendations of the United States Public Health Service and as indicated by standard medical practice. HIV-1 serologic screening shall be offered to beneficiaries presenting with sexually transmitted diseases, at sexually transmitted disease clinics, with alcohol and drug abuse problems, at alcohol and drug rehabilitation units, at prenatal clinics, and when clinically indicated.
- E6.2.6. Medical healthcare beneficiaries who are concerned about whether they have been exposed to HIV-1 should consult with local DoD medical personnel. As is the procedure for other medical problems (such as other sexually transmitted diseases, cardiovascular disease, breast cancer, and hepatitis), the beneficiary may obtain an appointment to discuss his or her concerns directly with the physician. The appropriate supporting tests, including laboratory evaluation, shall be determined by the physician.

E6.3. HEALTH EDUCATION

Health education shall be accomplished within the following program framework:

DoD HIV-1 AND/OR AIDS INFORMATION AND EDUCATION PROGRAM FRAMEWORK

1.	Goal	<u>Verification</u>	Assumptions
	Reduction in occurrence of HIV-1 infection in military peronnel and other DoD beneficiaries.	Statistics, as available, resulting from testing done by Services.	All AD tested periodically.
2.	<u>Objectives</u>		
	a. Provide information, education, and behavior-change programs on the prevention of AIDS.	DoD survey measuring knowledge and attitudes about high-risk behavior. Identified programs targeting recruits at point of entry; commmanders and supervisors; personnel overseas, alcohol and drug orientations, the ROTC, and Services academies.	Information, education, and behavior-change programs promote behavioral risk reduction; DoD survey shall continue. Mass media resources including print, radio and television (TV) are essential components of a comprehensive program.
	b. Implement program to provide information on the prevention of HIV-1 infection and AIDS to students in DoD schools.	Survey measuring knowledge and attitudes about HIV-1 infection and AIDS. Curriculum includes the prevention of HIV-1 infection.	
	c. Provide information, education, and motivation programs to those persons infected or whose behavior put them at high risk of infection (to include those who must not give blood), targeting patients in sexually transmitted disease clinics, drug and alcohol treatment programs, family planning clinics, and blood banks.	Annual Service-wide assessment of program availability, accessibility, and utilization.	Requires strong involvement of medical, nursing, drug and alcohol, and dental personnel.
	d. Provide information and education programs for healthcare personnel on HIV-1 and AIDS, addressing the needs of patients and staff.	Evaluation by Military Services of the extent to which appropriate healthcare providers are integrated in the prevention efforts.	Key to changing attitudes and/or behaviors is the provision of factural information from persons in whom the receipient has confidence.

DoD HIV-1 AND/OR AIDS INFORMATION AND EDUCATION PROGRAM FRAMEWORK, continued

2. <u>Objectives</u> <u>Verification</u> <u>Assumptions</u>

Assessment of knowledge and program implementation by physicians, nurses, dentists, and other healthcare providers.

Healthcare providers have current information about the disease. Infection control training is required.

Identified programs targeting healthcare personnel, drug and alcohol counselors, and emergency response personnel.

Activities

Information, education, and behavior change programs and resources targeting:

a. Person-to-Person

- (1) Persons infected or at increased risk (including family members).
- (2) Patients seen in sexually transmitted disease clinics, drug and alcohol treatment programs, prenatal clinics, clinical laboratories blood banks, family planning clinics, and other appropriate group clinics or classes.
- (3) Occupational health program patients, particularly at-risk occupational groups.

DoD HIV-1 AND/OR AIDS INFORMATION AND EDUCATION PROGRAM FRAMEWORK, continued

Activities

b. Groups

Department of Defense Dependents Schools' teachers and students; healthcare personnel; commanders and supervisors; drug and alcohol counselors; emergency personnel: police, fire, security, etc.; healthcare beneficiaries overseas; recruits at points of entry into the Services; drug and alcohol orientation and Service treatment programs; chaplains; parent, family, and youth support programs; ROTC and Service academies; family and community service centers; and child care providers.

c. Mass Media

Print media: newspapers journals, and posters printed under DoD sponsorship

Radio and TV.

E7. ENCLOSURE 7

PROCEDURE FOR EVALUATING T-HELPER CELL COUNT

E7.1. ANALYTICAL PROCEDURE

- E7.1.1. Each laboratory performing T-helper cell counts shall maintain a current and complete standard operating procedure manual. The absolute T- helper cell count is a product of the percentage of T-helper cells (defined as CD4 positive lymphocytes) and the absolute lymphocyte level. The percentage of CD4 positive lymphocytes is determined by immunophenotyping blood cells using flow cytometry instrumentation. The absolute lymphocyte count is determined using hematology instrumentation.
- E7.1.2. Flow cytometry instruments shall be equipped for two-color fluoro-chrome analysis with an electronic compensator to offset the spectral overlap of the most commonly used fluorochromes, fluorescein, and phycoerythrin. Additionally, equipment shall have logarithmic scale capability with a minimum measured output of 3 decades and shall provide simultaneous 4-parameter analysis including right-angle light scatter, forward-angle light scatter, green fluorescence, and red fluorescence.
- E7.1.3. Flow cytometry analysis shall be capable of distinguishing between the following cell surface phenotypic expressions: CD2, CD3, CD4, CD8, CD14, CD45, and a B lymphocyte marker of either CD19 or CD20 specificity. All monoclonal antibody reagents shall be conjugated with either fluorescein isothiocyanate or phycoerythrin. Due to the ready availability of directly conjugated monoclonal reagents, no indirect staining procedures shall be used for the above lymphocyte markers. A monoclonal antibody that does not universally identify CD4 cells in all specimens shall not be used for the determination of CD4 lymphocytes. Only reagents with specificity to CD2, CD3, CD4, CD8, CD14, CD19, CD20, and CD45 are acceptable under this procedure.
- E7.1.4. Blood specimens for the absolute lymphocyte count and lymphocyte immunophenotype shall be drawn during the same venipuncture between 0600 and 0900 hours. The absolute lymphocyte count shall be performed on an ethylenediamine tetraacetate anticoagulated whole blood specimen within 4 hours of specimen collection. The absolute lymphocyte count shall be determined on an automated hematology instrument with a locally verified interrun and intrarun coefficient of variation of less than 5 percent. The whole blood lysate procedure shall be used for flow cytometry cell preparations. Flow cytometry specimens shall be stained and lysed within a time period that has been locally demonstrated to yield an overall cell viability

greater than the 90 percent. Blood specimens shall be stained and lysed by a standard method that shall be detailed in the director of the laboratory's standard operating procedure manual. All blood specimens for cell surface phenotyping shall be analyzed for nonspecific binding with vendor-matched, isotype-matched, and conjugate-matched control antibody reagents for each test antibody used. As this standard applies to lymphocyte immunophenotyping, lymphocyte populations shall be defined by those cells gated on forward- and right-angle light scatter that are at least 95-percent positive for CD45 (the brightest CD45 population that is specific for lymphocytes) and no more than 5-percent positive for CD14.

E7.2. <u>INTERNAL QUALITY CONTROL PROGRAM</u>

- E7.2.1. Each laboratory shall maintain a comprehensive internal quality control program. Minimally, on each day of operation the following flow cytometry procedures or reagents shall be monitored:
- E7.2.1.1. Optical focusing and alignment of all lenses and light paths for forward-angle light scatter, right-angle light scatter, red fluorescence, and green fluorescence.
- E7.2.1.2. Fluorescent intensity beads, particles, or cells with fluorescence in the range of biological samples.
- E7.2.1.3. Fluorescent compensation beads, particles, or cells with fluorescence in the range of biological samples.
 - E7.2.1.4. A human blood control sample.
- E7.2.2. Each laboratory shall establish tolerance limits for each of the procedures or reagents in subparagraphs E7.2.1.1. through E7.2.1.4. of this enclosure, above. Appropriate corrective action shall be taken and documented when any quality control reagent exceeds established tolerance limits. Routine maintenance and function verification checks shall be accomplished expediently. The laboratory director shall review corrective and quality control records regularly.

E7.3. EXTERNAL QUALITY CONTROL PROGRAM

The Army is responsible for establishing and operating an external quality control program to evaluate the results reported by the flow cytometry laboratories. The external quality control program shall include a hematology survey to monitor the

performance of the absolute lymphocyte count and a flow cytometry survey to monitor the performance of each immunophenotyping procedure.

E7.4. <u>RECORDING AND REPORTING DATA</u>

The laboratory director shall review and verify the reported results. The laboratory report shall contain data from which absolute and relative values may be calculated for each lymphocyte subpopulation along with locally derived normal ranges inclusive of the fifth and ninety-fifth percentiles. The laboratory shall maintain permanent files of reports, internal and external quality control records, and instrument maintenance and performance verification checks.

E7.5. PERSONNEL QUALIFICATIONS

- E7.5.1. The importance of accurate flow cytometry determinations requires that all personnel involved with the flow cytometry instrumentation be properly trained.
- E7.5.2. The director of the flow cytometry laboratory shall hold a doctoral degree in a biologic science or be a physician, and shall possess experience in immunology or cell biology.
- E7.5.3. Alaboratory supervisor, if applicable, shall hold a bachelor's degree in a biological science and have at least 2 years of experience in flow cytometry.

E7.6. SAFETY

All laboratories shall comply with the biosafety level 2 standards established by the Centers for Disease Control. All procedures having the potential to create infectious aerosols shall be conducted within the confines of a Class II biological safety cabinet. Although certain specimen processing procedures may inactivate infectious agents, all material shall be treated as infectious throughout all procedures. All material generated in the processing and evaluation of blood specimens shall be decontaminated and disposed of according to established hazardous waste disposal policies.

E8. ENCLOSURE 8

HIV-1 TESTING OF DoD CIVILIAN EMPLOYEES

- E8.1.1. Requests for authority to screen DoD civilian employees for HIV-1 shall be directed to the ASD(FM&P). Only requests that are based on a host-nation HIV-1 screening requirement shall be accepted. Requests based on other concerns, such as sensitive foreign policy or medical healthcare issues, shall not be considered under this Directive. Approvals shall be provided in writing by the ASD(FM&P). Approvals shall apply to all the DoD Components that may have activities located in the host nation.
- E8.1.2. Specific HIV-1 screening requirements may apply to DoD civilian employees currently assigned to positions in the host nation, and to prospective employees. When applied to prospective employees, HIV-1 screening shall be considered as a requirement imposed by another nation that must be met before the final decision to select the individual for a position or before approving temporary duty or detail to the host nation. The Department of Defense has made no official commitment, for positions located in host nations with HIV-1 screening requirements, to those individuals who refuse to cooperate with the screening requirement or to those who cooperate and are diagnosed as HIV-1 seropositive.
- E8.1.3. DoD civilian employees who refuse to cooperate with the screening requirement shall be treated, as follows:
- E8.1.3.1. Those who volunteered for the assignment, whether permanent or temporary, shall be retained in their official position without further action and without prejudice to employee benefits, career progression opportunities, or other personnel actions to which those employees are entitled under applicable law or regulation.
- E8.1.3.2. Those who are obligated to accept assignment to the host nation under the terms of an employment agreement, regularly scheduled tour of duty, or similar and/or prior obligation may be subjected to an appropriate adverse personnel action under the specific terms of the employment agreement or other authorities that may apply.
- E8.1.3.3. Host-nation screening requirements, which apply to DoD civilian employees currently located in that country, also must be observed. Appropriate personnel actions may be taken, without prejudice to employee rights and privileges, to comply with the requirements.

- E8.1.4. Individuals who are not employed in the host nation, who accept the screening, and who are evaluated as HIV-1 seropositive shall be denied the assignment on the basis that evidence of seronegativity is required by the host nation. If denied the assignment, such DoD employees shall be retained in their current positions without prejudice. Appropriate personnel actions may be taken, without prejudice to employee rights and privileges, on DoD civilian employees currently located in the host nation. In all cases, employees shall be given proper counseling and shall retain all the rights and benefits to which they are entitled, including accommodations for the handicapped as in the ASD(FM&P) Memorandum and FPM Bulletin 792-42 (references (k) and (l)), and for employees in the United States (29 U.S.C. 794, reference (m)). Non-DoD employees should be referred to appropriate support service organizations.
- E8.1.5. Some host nations may not bar entry to HIV-1-seropositive DoD civilian employees, but may require reporting of such individuals to host-nation authorities. In such cases, DoD civilian employees who are evaluated as HIV-1 seropositive shall be informed of the reporting requirements. They shall be counseled and given the option of declining the assignment and retaining their official positions without prejudice or notification to the host nation. If assignment is accepted, the requesting authority shall release the HIV-1 seropositive result, as required. Employees currently located in the host nation may also decline to have seropositive results released. In such cases, they may request and shall be granted early return at Government expense or other appropriate personnel action without prejudice to employee rights and privileges.
- E8.1.6. Apositive confirmatory test by WB must be accomplished on an individual if the screening test (ELISA) is positive. Acivilian employee may not be identified as HIV-1 antibody positive, unless the confirmatory test (WB) is positive. The clinical standards in this Directive shall be observed during initial and confirmatory testing.
- E8.1.7. Procedures shall be established by the DoD Components to protect the confidentiality of test results for all individuals, consistent with the ASD(FM&P) Memorandum and DoD Directive 5400.11 (references (k) and (n)).
- E8.1.8. Tests shall be provided by the DoD Components at no cost to the DoD civilian employees, including applicants.
- E8.1.9. DoD civilian employees infected with HIV-1 shall be counseled appropriately.

E9. ENCLOSURE 9

PERSONNEL NOTIFICATION AND EPIDEMIOLOGICAL INVESTIGATION

E9.1. PERSONNEL NOTIFICATION

- E9.1.1. On notification by a medical health authority of an individual with serologic or other laboratory or clinical evidence of HIV-1 infection, the cognizant military health authority shall undertake preventive medicine intervention, including counseling of the individual and others at risk of infection, such as his or her sexual contacts (who are military healthcare beneficiaries), on transmission of the virus. The cognizant military health authority shall coordinate with the military and civilian blood bank organizations and preventive medicine authorities to trace back possible exposure through blood transfusion or donation of infected blood (ASD(HA) Memorandum, reference (o)) and refer appropriate case-contact information to the appropriate military or civilian health authority.
- E9.1.2. All individuals with serologic evidence of HIV-1 infection who are military healthcare beneficiaries shall be counseled by a physician or a designated healthcare provider on the significance of a positive antibody test. They shall be advised as to the mode of transmission of that virus, the appropriate precautions and personal hygiene measures required to minimize transmission through sexual activities and/or intimate contact with blood or blood products, and of the need to advise any past sexual partners of their infection. Women shall be advised of the risk of perinatal transmission during past, current, and future pregnancies. The infected individuals shall be informed that they are ineligible to donate blood and shall be placed on a permanent donor deferral list.
- E9.1.3. Service members identified to be at risk shall be counseled and tested for serologic evidence of HIV-1 infection. Other DoD beneficiaries, such as retirees and family members, identified to be at risk shall be informed of their risk and offered serologic testing, clinical evaluation, and counseling. The names of individuals identified to be at risk who are not eligible for military healthcare shall be provided to civilian health authorities in the local area where the index case is identified, unless prohibited by the appropriate State or host-nation civilian health authority. Such notification shall comply with the "Privacy Act of 1974" (Pub. L. No. 93-579 (1974), reference (p)). Anonymity of the HIV-1 index case shall be maintained, unless reporting is required by civil authorities.

E9.1.4. Blood donors who demonstrate repeatedly reactive ELISA tests for HIV-1, but for whom WB or other confirmatory test is negative or indeterminate, and who cannot be reentered into the blood donor pool shall be appropriately counseled.

E9.2. EPIDEMIOLOGICAL INVESTIGATION

- E9.2.1. Epidemiological investigation shall attempt to determine potential contacts of patients who have serologic or other laboratory or clinical evidence of HIV-1 infection. The patient shall be informed of the importance of case-contact notification to interrupt disease transmission and shall be informed that contacts shall be advised of their potential exposure to HIV-1. Individuals at risk of infection include sexual contacts (male and female); children born to infected mothers; recipients of blood, blood products, organs, tissues, or sperm; and users of contaminated intravenous drug paraphernalia. Those individuals determined to be at risk who are identified and who are eligible for healthcare in the military medical system shall be notified. Additionally, the Secretaries of the Military Departments shall provide for the notification, either through local public health authorities or by DoD healthcare professionals, of the spouses of Reserve component members found to be HIV-1-infected. Such notifications shall comply with the "Privacy Act of 1974" (Pub. L. No. 93-579 (1974), reference (p)). The Secretaries of the Military Departments shall designate all spouses (regardless of the Service affiliation of the HIV-1-infected Reservist) who are notified under this provision to receive serologic testing and counseling on a voluntary basis from MTFs under the Secretaries' of the Military Departments jurisdiction.
- E9.2.2. Communicable disease reporting procedures of civil authorities shall be followed to the extent consistent with this Directive through liaison between the military public health authorities and the appropriate local, State, territorial, Federal, or host-nation health jurisdiction.

E10. ENCLOSURE 10

RETENTION AND SEPARATION

E10.1. RETENTION

- E10.1.1. AD Service members with serologic evidence of HIV-1 infection shall be referred for a medical evaluation for documentation of fitness for continued service in the same manner as personnel with other progressive illnesses. Evaluation shall be conducted in accordance with the standard clinical protocol, as described in enclosure 2. Service members with serologic evidence of HIV-1 infection who are evaluated as physically fit for duty may not be separated solely on the basis of serologic evidence of HIV-1 infection.
- E10.1.2. Reserve component members with serologic evidence of HIV-1 infection are ineligible for extended AD (for a period of more than 30 days) except under conditions of mobilization. Reserve component members who are not on extended AD or who are not on extended full-time National Guard duty, and who show serologic evidence of HIV-1 infection, may be transferred involuntarily to the Standby Reserve only if they cannot be utilized in the Selected Reserve, as determined under paragraph 6.16. of the main body of this Directive, above.

E10.2. <u>SEPARATION</u>

- E10.2.1. AD Service members who are infected with HIV-1 and are determined to be physically unfit for further duty shall be retired or separated in accordance with the policies in DoD Directive 1332.18 (reference (g)).
- E10.2.2. AD Service members with serologic evidence of HIV-1 infection who are found not to have complied with lawfully ordered preventive medicine procedures for individual patients are subject to appropriate administrative and disciplinary action, which may include separation.
- E10.2.3. Separation of AD Service members with serologic evidence of HIV-1 infection under the plenary authority of the Secretary of the Military Department concerned, if requested by the Service member, is permitted.
- E10.2.4. Reserve members with serologic evidence of HIV-1 infection may be transferred to the Standby Reserve or separated when they fail to provide from their civilian physician an evaluation conforming to the protocol described in enclosure 2.

Transfer or separation may occur only after the Service member has been allowed a reasonable period of time, as determined by the Secretary of the Military Department, to respond to such requests. If separated, the characterization of service shall never be less than that warranted by the Service member's service record.

E10.2.5. AD Service members determined to have been infected with HIV-1 at the time of enlistment are subject to discharge for erroneous enlistment.